510(K) SUMMARY

Corentec Co., Ltd.

LOSPA Tibial Base Plate

5th April, 2012

ADMINISTRATIVE INFORMATION

Manufacturer Corentec Co., Ltd.
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	LOSPA Tibial Base Plate
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Regulations:	21 CFR 888.3560
Class:	II
Product Codes:	JWH
Classification Panel:	Orthopedic Products Panel
Reviewing Branch:	Orthopedic Devices Branch

INTENDED USE

The intended use of the modified device [LOSPA Tibial Base Plate] has not changed as a result of the modification of the predicate device cleared under Lospa Total Knee System, K110404.

The LOSPA Tibial Base Plate which is a component of LOSPA Total Knee System is intended for use in total knee arthroplasty surgery for the following indications
•Painful, disabling joint disease of the knee resulting from non-inflammatory degenerative Joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis;
•Post-traumatic loss of knee joint configuration and function;
•Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
•Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure.
The LOSPA Tibial Base Plate is intended for cemented use only.

DEVICE DESCRIPTION

The LOSPA Tibial Base Plate is a component of "LOSPA Total Knee System" cleared under K110404 which consists of Femoral Components, Tibial Base plate, Tibial Insert, Patellar Components and Instrumentation – LOSPA Total Knee Instrumentation for use with the system implant components

The current premarket notification is related to the modification of LOSPA Tibial Base Plate design. The modification is specific to the KEEL and the design is similar to predicate device in K110404 and other approved device such as Stryker Scorpio 'NRG' Knee (K030978). Similar to predicate device the tibial base plates (or trays), are available in nine (9) sizes to provide optimal tibial coverage. The tibial base plates are designed for use in either the left or right side, and with either CR or PS femoral components or corresponding tibial inserts.

All tibial base plate components are manufactured from cobalt-chromium-molybdenum alloy conforming to ASTM F75, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).

The AP width ranges from 36 mm to 54 mm, and the ML width ranges from 55 mm to 84 mm. The underside of the base plate features a central keel and stem; the length of the stem is either 35 mm or 40 mm. The stem with keel design is intended to improve the initial stability. In addition, the posterior slope of the keel and stem helps to increase rotational resistance. The base plate is designed to fully capture and lock the polyethylene insert. The surface of the tibial base plate that interfaces with the polyethylene insert includes a ground finish to minimize back side wear of tibial inserts.

\SUBSTANTIAL EQUIVALENCE

LOSPA Tibial Base Plate is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent, as below,.

- **Corentec Co., Ltd.**, Eaum Total Knee System (*now renamed as LOSPA Total Knee System*) cleared under K110404
- **Howmedica Osteonics Corp. (Stryker)** Scorpio 'NRG' Knee cleared under K030978

PERFORMANCE DATA

Performance testing was carried out to demonstrate substantial equivalence and included methods described in the following standards: ASTM F1800 / ISO14879-1 and ISO 21536. Mechanical testing of the subject device consisted of fatigue (endurance) testing. The Tibial Base Plate performed similar to the predicate device submitted under K110404. The modified instrument, tibial keel punch, was also tested and validated.

Any differences in technological characteristic between the subject and predicate devices do not raise new issues of safety or efficacy.

Overall, the LOSPA Tibial Base Plate has similarities to the predicate device/s with the same intended use, same fundamental scientific technology, same operating principles, same materials and are supplied Sterile.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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MAY - 3 2012

Re: K121037
Trade/Device Name: LOSPA Total Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: April 5, 2012
Received: April 5, 2012

Dear Mr. Daniel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

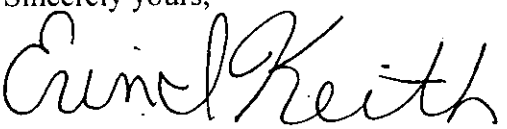
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K121037

Device Name: LOSPA Tibial Base Plate

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The LOSPA Tibial Base Plate which is a component of *Lospa Total Knee System* is intended for use in total knee arthroplasty surgery for the following indications:

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- Post-traumatic loss of knee joint configuration and function;
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability;
- Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous arthroplasty procedure.

The LOSPA Tibial Base Plate is intended for cemented use only.

Prescription Use: X AND / OR Over-The Counter Use: ———
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121037